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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,752	04/05/2001	Leonard P. Guarente	0050.1491-005	1365

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[REDACTED] EXAMINER

BRUSCA, JOHN S'

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/18/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No.	Applicant(s)
	09/826,752	GUARENTE ET AL.
Examiner	Art Unit	
John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 March 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13-31 is/are pending in the application.
- 4a) Of the above claim(s) 14,16-18,23,25-27 and 31 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13,15,19-22,24 and 28-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 April 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3_11</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of species 2, heat shock resistance phenotype in Paper No. 16 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 14, 16-18, 23, 25-27, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 16. It is further noted that claim 23 was incorrectly listed as a generic claim in the Office action mailed 31 January 2003, and should have been listed as a claim drawn to the growth to high saturation density phenotype species.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 10 January 2003 contains citations ASS and ATT which were not listed with an author and place (database) of publication as required by 37 CFR 1.98. Therefore these references were marked as not considered. The contents of the references have nevertheless been reviewed and placed in the application file.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 13, 15, 19-22, 24, and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 15, 19-22, 24, and 28-30 are indefinite for recitation in claim 13, line 7 of the phrase “is a function of stress survival” because it is not clear how a phenotypic property can be a function. The rejection would be overcome by amending claim 13 to recite “is stress survival.”

For the purpose of examination, the claims have been assumed to incorporate the suggested amendments.

***Claim Rejections - 35 USC § 102***

6. For the purpose of examination the term “agent” in claim 13 as defined on page 31 of the specification is interpreted to exclude mutagens.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 13, 21, and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Fleming et al.

The claims are drawn to a method of assaying the effect of an agent on the lifespan of a eukaryotic cell that is under stress. In some embodiments the eukaryotic cell is genetically altered to have a different capacity for mitotic division. In some embodiments the cell is cultured for greater than the capacity of cell division prior to treatment with the agent.

Fleming et al. reviews the role of oxidative stress in aging in Drosophila on pages 267-269. On pages 269-272 Fleming et al. shows that production of transgenic Drosophila organisms

comprising a bovine superoxide dismutase (SOD) gene. The bovine gene corresponds to the agent recited in the claimed invention. Fleming et al. shows in figures 1 and 2, and pages 269-272 that the transgenic Drosophila have an increased lifespan when placed under stress due to paraquat or 100% oxygen.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleming et al.

The claims are drawn to a method of assaying the effect of an agent on the lifespan of a eukaryotic cell that is under the stress of heat shock.

Fleming et al. reviews the role of oxidative stress in aging in Drosophila on pages 267-269. On pages 269-272 Fleming et al. shows that production of transgenic Drosophila organisms comprising a bovine superoxide dismutase (SOD) gene. The bovine gene corresponds to the agent recited in the claimed invention. Fleming et al. shows in figures 1 and 2, and pages 269-272 that the transgenic Drosophila have an increased lifespan when placed under stress due to paraquat or 100% oxygen. Fleming et al. reviews the effect of heat shock on ageing on pages 273-277. Fleming et al. shows that heat shock induces expression of heat shock proteins, and on page 275 discusses treatment of Drosophila organisms with an agent consisting of canavanine to induce a heat shock response. Fleming et al. discuss the induction of SOD upon heat shock on page 276. Fleming et al. shows the effect of heat shock on survival for old and young Drosophila organisms in figure 5. Fleming et al. does not show the method of claim 15 in which cells treated with an agent are stressed by heat shock and length of survival is measured.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Fleming et al. by determining the effect of heat shock on the wild type and transgenic Drosophila organisms disclosed in Fleming et al. because such a determination would allow for further insights into the role of SOD, heat shock, and ageing.

12. Claims 13, 19, 20, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleming et al. in view of Lundblad et al. (reference AW2 in the information disclosure statement filed 04 June 2001).

The claims are drawn to a method of assaying the effect of an agent on the lifespan of a eukaryotic cell that is under stress. In some embodiments the relative mitotic capacities of treated and untreated cells are determined, the cell is a yeast cell, and the stress is heat shock.

Fleming et al. reviews the role of oxidative stress in aging in Drosophila on pages 267-269. On pages 269-272 Fleming et al. shows that production of transgenic Drosophila organisms comprising a bovine superoxide dismutase (SOD) gene. The bovine gene corresponds to the agent recited in the claimed invention. Fleming et al. shows in figures 1 and 2, and pages 269-272 that the transgenic Drosophila have an increased lifespan when placed under stress due to paraquat or 100% oxygen. Fleming et al. reviews the effect of heat shock on ageing on pages 273-277. Fleming et al. shows that heat shock induces expression of heat shock proteins, and on page 275 discusses treatment of Drosophila organisms with an agent consisting of canavanine to induce a heat shock response. Fleming et al. discuss the induction of SOD upon heat shock on page 276. Fleming et al. shows the effect of heat shock on survival for old and young Drosophila organisms in figure 5. Fleming et al. does not show the method of claim 15 in which cells treated with an agent are stressed by heat shock and length of survival is measured. Fleming does not show direct measurement of mitotic potential or use of yeast cells.

Lundblad et al. shows in the abstract that yeast cells mutated in the EST1 gene have a shortened lifespan. Lundblad et al. shows on page 637 the treatment of yeast cells with defective EST1 genes. Lundblad et al. shows measurement of mitotic potential in yeast strains in figures 3

and 6 and in the experimental procedures section on pages 641-642 for the purpose of determining the effect of introduced mutations on mitotic potential.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Fleming et al. by use of the yeast cells and mitotic potential methods of Lundblad et al. because such a modification would allow for further insights into the role of SOD and ageing in yeast cells.

13. Claims 13, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleming et al. in view of Lundblad et al. as applied to claims 13, 19, 20, 22, and 24 above, and further in view of Pringle (reference ARR in the information disclosure statement filed 10 January 2003) in view of Muller (reference AII in the information disclosure statement filed 10 January 2003).

The claims are drawn to a method of assaying the effect of an agent on the lifespan of a eukaryotic cell that is under stress by use of fluorescent cell surface labeling.

Fleming et al. in view of Lundblad et al. as applied to claims 13, 19, 20, 22, and 24 above does not show use of fluorescent cell labeling.

Muller shows on page 1 that the lifespan of a yeast cell correlates with the number of bud scars on the cell. Muller shows use of bud scar counts to determine the age of yeast cells in Table 2.

Pringle et al. shows on pages 378-380 the use of fluorescent dyes to observe bud scars.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Fleming et al. in view of Lundblad et al. as applied

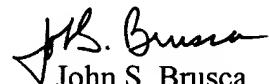
to claims 13, 19, 20, 22, and 24 above by use of the fluorescent dye method of determining the age of yeast cells to allow for a determination of the lifespan of the observed cells.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb  
April 16, 2003